K080689

JUL - 9 2008

510(k) Summary
for
Spectra Therapy Spectra A1000 Laser Device

1. SPONSOR

Premier Dynamics, Inc.
3863 Rochester Rd,
Troy, MI 48083

Contact Person: John Stephan
Telephone: 248-321-2029

Date Prepared: March 10, 2008

2. DEVICE NAME

Proprietary Name:	Spectra A1000 Laser Device
Common/Usual Name:	Heating lamp
Classification Name:	Heating lamp for adjunctive use in pain therapy

3. PREDICATE DEVICES

Escada TerraQuant MQ2000 Laser Therapy Device K043055

4. DEVICE DESCRIPTION

The Spectra Therapy Spectra A1000 is an infrared lamp intended to provide topical heating. The Spectra A1000 is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle pain and/or the temporary relaxation of muscle.

The Spectra A1000 System houses multiple photo energy devices. The photo devices consist of 4 dual [infrared and RED visible] lasers combined with a cluster of 8 visible RED LED's, and 8 Infrared LED's and a yellow indicator lamp.

The Spectra A1000 Laser Therapy Device consists of a docking unit, a USB and laser port, a key port and a key. The laser and light therapy releases radiation with wing wavelengths, all of which fall within the infrared range as defined in 21 CFR 890.5500.

5. INTENDED USE

The Spectra Therapy Spectra A1000 is an infrared lamp intended to provide topical heating. The Spectra Therapy Spectra A1000 is indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Spectra A1000 device and the predicate TerraQuant MQ2000 Laser Therapy System device are also substantially equivalent in technological characteristics in that they are both hand-held, heating laser diodes, and/or infrared lamps, that deliver low level laser light to various anatomic areas. Both the output power and output wavelength of the proposed device are within the range of the predicate device. Tissue Temperature and electrical safety and EMC/EMI testing have been performed demonstrating that the Spectra A1000 Laser Device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2008

Premier Dynamics, Inc.
% Mr. John J. Stephan
General Manager
3863 Rochester Road
Troy, Michigan 48083

Re: K080689
Trade/Device Name: Spectra Therapy Spectra A1000 Laser Device
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: June 10, 2008
Received: June 11, 2008

Dear Mr. Stephan:

This letter corrects our substantially equivalent letter of July 9, 2008

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number No # K080689

Device Name: Spectra Therapy Spectra A1000 Laser Device

Indications for Use:

The Spectra Therapy Spectra A1000 is an infrared lamp intended to provide topical heating. The Spectra Therapy Spectra A1000 is indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080689